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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,932	02/28/2002	John F. Corson	10020334-1	3957

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/086,932	CORSON ET AL.
	Examiner	Art Unit
	Maureen M. Wallenhorst	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/18/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the "same-dye reference array" and the "stable-dye reference arrays" are indefinite and unclear for several reasons. Firstly, it is not clear how these arrays are different from one another. Do these arrays contain different chemical dyes from one another or different concentrations of the same dye? Secondly, it is also not clear what the "same-dye" is the same as. Thirdly, it is not clear how the stable dye is "stable" since the conditions of stability have not been defined. In other words, it is not clear what the stable dye is stable relative to. The same dye? The descriptions given for the same-dye reference array and stable-dye reference array on page 14 of the specification do not serve to properly define these arrays in the claims since these descriptions state that the stable dye reference array has more stable fluorescence-emission characteristics over repeated scans than the same-dye reference array. However, since the original, baseline stability level of the same dye has not been defined, it is unclear what defines being "more stable" than the baseline same dye. In other words, since it is unclear how long the

same dye maintains the same fluorescence-emission characteristics over repeated scans, it is not clear how long the stable dye maintains the same fluorescence-emission characteristics over repeated scans above and beyond that provided by the same dye. See these same problems throughout claims 1-10, especially independent claim 6. Claim 1 is also indefinite since it is not clear how the first molecular array scanner is calibrated with the second, reference molecular array scanner using a same-dye reference array. It is not clear whether both the second, reference molecular array scanner and the first molecular array scanner scan the same-dye reference array in this step or whether only one of these scanners scans the same-dye reference array. How is one scanner calibrated to the other? See this same problem in claim 6.

On lines 10-11 of claim 2, the phrase "as if it were scanned in the reference scanner for the first time" is indefinite since it is not clear what this phrase is referring to. Does "it" refer to the same-dye reference array? In addition, it is not clear why the first molecular array scanner is adjusted to produce the expected intensity as if the same dye reference array were scanned in the reference scanner for the first time when the second step of claim 2 recites that the expected intensity is for when the same dye reference array is scanned by the reference scanner in a subsequent scan to the first scan, not for the actual first scan. See these same problems in claim 7.

Claim 3 is indefinite since it is not understood how the function of signal intensity decrease per scan of the same dye reference array is used to calculate the expected intensity when the last step of claim 3 does not recite the use of this function in determining the expected intensity. See this same problem in claim 8.

Claims 7-9 are indefinite since these claims do not further limit the structural features of the apparatus as recited in independent claim 6. Rather, claims 7-9 recite method limitations.

Claim 10 is indefinite since on line 2, it recites "by the system of claim 1". However, claim 1 does not recite a system, but rather a method. Claim 10 should depend from claim 6.

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 5 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 5 and 10, as currently written, are drawn to signal intensity data, which is merely a compilation or arrangement of data, which is deemed to be non-functional descriptive material and non-statutory subject matter. See MPEP 2106, (IV)(B)(1).

5. Claims 1 and 6 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action since none of the prior art of record teaches or fairly suggests a method and apparatus for calibrating a first molecular array scanner with a second, reference molecular array scanner that comprises the steps of initially calibrating the first molecular array scanner with the second, reference molecular array scanner by using an array that contains thereon a first dye, wherein the first dye is the same as a dye used to label probe molecules in actual molecular array experiments, and maintaining the initial calibration of the first molecular array scanner by scanning with the first molecular array scanner one or more arrays containing thereon a second dye, wherein the second dye is different chemically from the first dye and has more consistent fluorescence–emission characteristics over repeated scans than the first dye.

6. Claims 2-4 and 7-9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Corson, Schermer et al (WO 01/06238), Wolber et al (US 2003/0065449 and EP 1,186,673), Holcomb et al, Staton et al and Noblett who all teach of different methods for calibrating molecular array scanners.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 28, 2004

Maureen M. Wallenhorst
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